REMARKS

Upon entry of this amendment, claims 31-43 and 47-51 are pending.

Claims 1-3, 7-8, 10-30 and 44-46 are hereby canceled. Claims 15-24 which previously were withdrawn following a restriction requirement are also canceled.

Claims 31-39 have been amended to begin with a definite article as suggested by the Examiner. Claims 31-39 were also amended to require at least residues 1-8 of SEQ ID NO:1 or 2 and not 1, 2, or all 3 carboxyterminal residues of the corresponding sequence. This amendment and new claims 52-54 are supported by disclosure at page 1, lines 19-23; page 2, lines 4-11; page 2, lines 25-27; and page 7, lines 1-2, of the specification. New claims 47-51 are supported by disclosure at page 10, line 14, to page 11, line 7, of the specification.

No new matter is added by this amendment. Applicants reserve the right to prosecute amended, cancelled, and withdrawn claims or claims having breadth and scope similar to those as originally filed in this or another application having the same priority date as the present application.

The claims are supported by the written description

The Examiner in the Office Action (p. 3, lines 3-4, 12-13, and p. 4, lines 18-20) maintains rejection of claims under 35 U.S.C. 112, first paragraph, stating that "...the specification broadly describes as a part of the invention polypeptides consisting of the polypeptides SEQ ID Nos: 1, 2, 12 and 13...the specification provides insufficient written description to support the genus encompassed by the claim...Claim 31 broadly describes a genus of substance P peptide fragments and does not provide a structure description of the peptides encompassed by the claim."

Claim 31 has now been amended to require residues 1-8 of SEQ ID NO:1 or 2, but not residue 9, 10, or 11 of the corresponding reference sequence. Claims 31-35 have been similarly amended to require residues 1-9 (and not residues 10 and 11) or to require residues 1-10 (and not residue 11) of SEQ ID NO:1 or 2.

Applicants submit that the amended claims meet the requirements of the Written Description Guidelines and therefore request withdrawal of this rejection.

The claims are fully enabled

Claims 1, 8 and 31-39 were previously rejected for lack of enablement and overbreadth.

The Examiner states in section 4, p. 7 of the Office Action:

> The specification is enabling only for the polypeptides of SEQ ID Nos: 1 and 2 as disclosed in the specification....There is no guidance provided as to which amino acids can be added, deleted or substituted and the polypeptide would retain its biological function. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity requires a knowledge with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved....

Claims 1 and 8 were canceled, and claims 31-39 were amended to require residues 1-8 of SEQ ID NO:1 (or 2) and to require that 1, 2, or all 3 carboxyterminal amino acids of the corresponding sequence are not present. On page 6, line 33, to page 7, line3, the specification teaches:

> The antimicrobial activity of an SP peptide is unrelated to SP receptor binding. SP receptor binding involves the carboxy-terminal end of SP. The carboxy-terminal 1, 2, or 3 amino acids of SP are not required for antimicrobial activity.

The specification further discloses examples of antimicrobial SP fragments (that do not bind to a SP-receptor) at page 12, lines 4-29:

> deletion or substitution one or more of the three carboxy-terminal residues (Gly-Leu-Met) associated with affinity of the SP peptides to a specific SP receptor on cells of the immune system assures that possible undesired side affects of systemic SP administration (e.g., SP-receptor mediated activities such as pain, inflammation, and swelling) are reduced or eliminated

The amended claims now specify exactly which amino acids are required to retain biological function, i.e., antimicrobial activity, and which amino acids are tolerant of modification while still retaining biological activity. Applicants therefore submit that the amended claims are

commensurate with the scope of the disclosure provided in the orginally-filed specification. Withdrawal of this rejection is respectfully requested.

Claims as amended are novel over the prior art

Applicants acknowledge the Examiner's withdrawal of prior rejections of claims 1-11 under 35 U.S.C. 102(b) in view of the references cited in the previous Office Action.

Rosengurt et al. (WO 88/07551)

The Examiner maintains rejection of claims 1-3, 7, 10-13, 24-27, 29-30 and 44-46 under 35 U.S.C. 102(b) in view of Rosengurt et al.

Claims 1-3, 7, 10-13, 24-27, 29-30 and 44-46 have been cancelled therefore this rejection is moot.

Hörig et al. (WO 83/01251)

The Examiner maintains rejection of claims 1-3, 7, 10-13, 24-27, 29-30 and 44-46 under 35 U.S.C. 102(b) in view of Horig et al.

Claims 1-3, 7, 10-13, 24-27, 29-30 and 44-46 have been cancelled therefore this rejection is moot.

Maszczynska et al. (Analgesia 3: 258-268, 1998)

Claims 1-2, 7, 11, 14, 24, 26, 28-34, 36, 38, and 41-46 were rejected for anticipation by Maszczynska et al. Claims 1-2, 7, 11, 14, 24, 26, 28-30 have been canceled. Claim 31 has been amended to require residues 1-8 of SEQ ID NO:1 and to lack one or more of the 3 carboxyterminal residues of SEQ ID NO:1 (i.e., residues 9, 10, or 11 of SEQ ID NO:1). Dependent claims were amended to require residues 1-9 (but not 10-11) and residues 1-10 (but not 11). Maszczynska et al. fail to describe the SP fragments now required by the amended claims. Therefore, this rejection should b withdrawn.

CONCLUSION

On the basis of the amendments and remarks, Applicants respectfully submit that the pending claims and specifications are in condition for allowance. If there are any questions

regarding these amendments and remarks, the Examiner is invited and encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

Dated: July 7, 2003

Ingrid A. Beattie (Reg. No. 42,306)
Sonia K. Guterman (Reg. No. 44,729)
Attorneys for Applicants
c/o MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.
One Financial Center
Boston, Massachusetts 02111
Tel: (617) 542-6000
Fax: (617) 542-2241

TRA 1810169v1